UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA Office of Pesticide Programs

**Antimicrobials Division (AD)**
September 13, 2013

**SUBJECT:** Zinc Oxide
**Guideline:** OCSPP 830.1620
Description of Production Process
Particle size, fiber length, and diameter distribution

| | |
|---|---|
| Applicant: | **Arch/Lonza** |
| EPA Reg. No.: | 62190-29 |
| Product Name | Chemonite Part C |
| DP Barcode: | 413186 |
| MRID : | 49085501 |
| Active Ingredient on OPPIN | Zinc oxide |
| % Active | 97% |
| PC Code | 088502 |
| CAS# | 1314-13-2 |

FROM: Chris Jiang
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang
9/13/13

THRU: Karen Hicks, Lead
Acute Toxicity/Product Chemistry Team
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Chris Jiang for K.PH
9/13/13

TO: Tom Luminello, Jr.
Regulatory Management Branch II
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Background

The data package consists of:

1. Transmittal Document signed by John French of Arch/Lonza
2. Particle size analysis using Chemonite Part C, OCSPP 830.1620 – Description of Production Process: Particle size, fiber length, and diameter completed on March 20, 2013
3. Particle size analysis of 5 batches of Zinc Oxide powder sample by American Chemet Corporation, East Helena MT

| MRID | Citation | Receipt Date |
|---|---|---|
| 49085501 | Zinc Oxide: Chemonite Part C Manufacturing Process Report and Particle Size Report | 3/21/2013 |

Good Laboratory Practices Statement:

This study was done according to GLP requirements.

Particle Size Distribution Table

| Item | Description | | | | | Comment |
|---|---|---|---|---|---|---|
| **Identity of Test Material** | | | | | | |
| Composition | Zinc Oxide | | | | | |
| Source | American Chemet Corporation | | | | | |
| Lot/Batch ID | 87096, | 87097 | 87098 | 87099 | 87100 | |
| **Sample Preparation** | | | | | | |
| Sample Amount | Enough | | | | | |
| Dispersion Medium | Reagent alcohol 200 proof (Pharmco-AAPR) / Aerosol OT solution | | | | | |
| Dispersion Equipment | Cole-Parmer 8891 sonication machine | | | | | |
| Duration of Dispersion Treatment | 1 second | | | | | |
| Dispersion Verification | Repeat at 1 second duration as necessary till a 70-90% measuring range is achieved. | | | | | |
| **Analytic Method** | | | | | | |
| Measurement Principle | Light scattering | | | | | |
| Instrument/Model | HORBA LA-910 Particle analyzer | | | | | |
| Software Version | Windows ™ WET (LA-910) ver. 3.72 | | | | | |
| Graphical Representation | Frequency Distribution diameter vs. frequency | | | | | |
| Limits of Measurement (min/max) | Not provided | | | | | |
| Calibration or Standardization Procedure (reference materials) | Calibrated using blank setting | | | | | |
| Precision: Repeatability or Reproducibility | Not provided | | | | | |
| **Results** | | | | | | |
| Distribution Basis (mass, number, or volume) | diameter | | | | | |
| | | | | | | |
| Mean Diameter (µm) | 1.6559 | 1.8348 | 1.1614 | 1.1686 | 1.8297 | |
| 10% size (µm) | 0.6243 | 0.6781 | 0.3207 | 0.3207 | 0.3615 | |
| 50% size (µm) | 1.3571 | 1.4576 | 0.8779 | 0.8750 | 1.2264 | |
| 90% size (µm) | 3.1112 | 3.5185 | 2.3380 | 2.3624 | 3.9650 | |
| Min/max of Size Range (µm) | 0.1-10 µm | | | | | |
| % less than 0.1 µm | N/A | | | | | |
| **Additional Information/Comments** | | | | | | |
| The product has particles of no concern. | | | | | | |